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International application number: PCT/US2004/030056

International filing date: 15 September 2004 (15.09.2004)

Document type: Certified copy of priority document

Document details: Country/Office: US  
Number: 60/502,993  
Filing date: 15 September 2003 (15.09.2003)

Date of receipt at the International Bureau: 26 March 2007 (26.03.2007)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)



World Intellectual Property Organization (WIPO) - Geneva, Switzerland  
Organisation Mondiale de la Propriété Intellectuelle (OMPI) - Genève, Suisse

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# THE UNITED STATES OF AMERICA

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*March 15, 2007*

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**APPLICATION NUMBER: 60/502,993**

**FILING DATE: *September 15, 2003***

**RELATED PCT APPLICATION NUMBER: *PCT/US04/30056***

**THE COUNTRY CODE AND NUMBER OF YOUR PRIORITY APPLICATION, TO BE USED FOR FILING ABROAD UNDER THE PARIS CONVENTION, IS *US60/502,993***



Certified by

Under Secretary of Commerce  
for Intellectual Property  
and Director of the United States  
Patent and Trademark Office

# PROVISIONAL APPLICATION COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION under 37 C.F.R. § 1.53(b)(2).

22368 U.S. PTO  
60/502993  
09/15/03

Attorney Docket No. <u>4396-031824</u>		Type a plus sign (+) inside this box →
INVENTOR(s)/APPLICANT(s)		
LAST NAME, FIRST NAME, MIDDLE INITIAL	RESIDENCE (CITY AND EITHER STATE OR FOREIGN COUNTRY)	
COWDEN, Ralph A., III LAU, Janey ROBERTS, James C., Jr. KEITH, Alec	Honolulu, Hawaii Kaneohe, Hawaii Toledo, Ohio Hilo, Hawaii	
TITLE OF THE INVENTION (280 characters max)		
"NUTRITIONAL SUPPLEMENT AND PROTOCOL"		
CORRESPONDENCE ADDRESS		
Webb Ziesenheim Logsdon Orkin & Hanson, P.C. 700 Koppers Building, 436 Seventh Avenue Pittsburgh, Pennsylvania 15219-1818, United States of America Telephone No.: (412) 471-8815, Facsimile No.: (412) 471-4094		
ENCLOSED APPLICATION PARTS (check all that apply)		
<u>4</u> Number of Pages in Specification		Other (specify) _____
Number of Sheets of Drawing(s)		Other (specify) _____
METHOD OF PAYMENT (check one)		
<input checked="" type="checkbox"/> A check or money order is enclosed to cover the Provisional filing fees (\$160.00 Large Entity; \$80.00 Small Entity). <input checked="" type="checkbox"/> Small Entity Status is asserted for this application under 37 C.F.R. § 1.27. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees required for filing this application to Deposit Account No. 23-0650. Please refund any overpayment in the form of Electronic Funds Transfer to the bank account of record for Webb Ziesenheim Logsdon Orkin & Hanson, P.C. An original and two copies of this sheet are enclosed.		
PROVISIONAL FILING FEE AMOUNT(S) \$ <u>80.00</u>		

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☒ No.

☐ Yes, the name of the U.S. Government agency and the Government contract No. are: \_\_\_\_\_

Respectfully submitted,

SIGNATURE Barbara E. Johnson Date 9/15/03

TYPED NAME Barbara E. Johnson Registration No. 31,198

☐ Additional inventors are being named on separately numbered sheets attached hereto.

## PROVISIONAL APPLICATION FILING ONLY

**PROVISIONAL PATENT APPLICATION**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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IN RE APPLICATION OF:

ATTORNEY DOCKET NUMBER:

Ralph A. COWDEN, III et al.

4396-031824

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ENTITLED:

**“NUTRITIONAL SUPPLEMENT AND PROTOCOL”**

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To: **Mail Stop Provisional Patent Application**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**EXPRESS MAIL CERTIFICATE**

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Date of Deposit September 15, 2003

I hereby certify that the following attached papers and fee

**PROVISIONAL APPLICATION COVER SHEET (1 p. in trip.);**  
**SPECIFICATION (4 pp.);**  
**AND A CHECK IN AMOUNT OF \$ 80.00 TO COVER THE FILING FEE.**

are being deposited with the United States Postal Service “Express Mail Post Office to Addressee” service under 37 C.F.R. § 1.10 on the date indicated above and are addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Anna Rosenstein

(Typed name of person mailing paper or fee)



(Signature of person mailing paper or fee)

## COMBINATIONS OF PRODUCTS:

This is a unique system designed to detox, help destroy microbicrobials, replenish the body, and boost the immune system. Our system includes

Edtatate, a mouth rinse to be used for one month before adding other ingredients

A, Detox

B. Cell Replenish

C. Immune System Booster

### EDTATATE, an ANTIMICROBIAL ADDITIVE to be added to your own mouth rinse

**Directions:** Each packet will contain 3 tablet of 370 mg each that are designed to dissolve in any variety of mouth rinse products,

Dissolve 1 tablet for every mL 16 Fl OZ (1 pint) 473 mL of mouth rinse. Following brushing, rinse with 1 - 3 teaspoons full strength for 30 seconds. Note: This pill may not completely dissolve in mouthwash containing an alcohol level above 9 % and some residue may be left on the bottom. This just means the pill was not absorbed 100 % and the rinse may not be as effective as bottles with less or no alcohol content. Follow guidelines on your own mouth rinse for directions and safety.

<i>Ingredients</i>	<i>Each</i>	<i>Adjusted Range</i>
EDTA	445 mg	200 to 900 mg
Vitamin C	15 mg	from 5 - 50 mg
Lysozyme	10 mg	from 5 to 30 mg

#### *Excepients*

Croscarmellose Sodium

Magnesium Stearate

TOTAL WEIGHT 700 mg

EDTA breaks down the plaque on your teeth. Lysozyme is an enzyme that attacks the carbohydrate chains forming protective cell walls of bacteria and causes the bacteria to burst under their own internal pressure. Vitamin C is a powerful antioxidant. This mouthwash is unique in its combination of products and uses a tablet that will dissolve in your own mouth rinse. Since most bacteria starts in the mouth and goes all over your body, this unique additive will begin to eliminate disease potential at the point of entry to help remove the plaque, and dissolve the viruses and bacteria in your mouth.

You will receive ample supply of the mouthwash for you and your partner. This will help prevent the recurrence of nanobacteria and the exchange of bacteria between partners.

## A. DETOX AND DESTROY BACTERIA AND ENVIRONMENTAL TOXINS

**Directions:** Serving per container 40 tablets for a 30-day supply.

**Suggested use:** Follow this regimen: As a dietary supplement, take Monday through Friday -- 1 tablet AM and 1 tablet PM for a total of 2 tablets daily with water. Do not take on weekends and resume regimen on Monday.

<b>Ingredients</b>	<b>Each</b>	<b>Daily</b>	<b>Adjusted Range</b>
EDTA	400 mg	800 mg	300 - 1600 mg daily
Ascorbic Acid	100 mg	200 mg	50 - 400 mg daily
DMSA	5 mg	10 mg	10 - 30 mg daily

### **Excepients**

Microcrystalline Cellulose

Silicon Dioxide

Magnesium stearate

Di-Calcium Phosphate

TOTAL WT w/excepients 1000 mg 2000 mg

Uniqueness of this product is the enteric coated EDTA tablet that is the first on the market to break down in the small intestine rather than the stomach. The recommended use is 5 days on and two days off as a regimen. In addition, DMSA is added to the ingredients to further detox the body. Also, Vitamin C is added as a powerful antioxidant and now recommended by the FDA.

EDTA (ethylenediamine tetra-acetic acid) complexes toxins and removes these toxins molecule by molecule from the body. Toxins come from the environment we live in --- they are in the air, water, and food we consume. According to the sciences of physics and chemistry, these transition elements are highly reactive and while some transition elements are essential, others are toxic. EDTA works similarly to a biological catalyst (enzyme) that help the body naturally get rid of toxins. The FDA approved the use of EDTA over 50 years ago for removing lead, aluminum, cadmium and other unwanted toxins from the body that contribute or cause abnormal physical and chemical reactions. EDTA improves calcium and cholesterol metabolism by eliminating toxic metallic catalysts that can damage cell membranes by producing oxygen free radicals. It further inhibits blood clotting and is routinely added to blood samples that are drawn for testing purposes.

DMSA (dimercaptosuccinic acid) removes mercury from the body and eliminates it through the urine and feces. The literature also states that it further helps rid the body of harmful mycoplasmas.

## **B. CELL REPLENISHER -- PHOSPHATIDYL LIPID and ALPHA LIPOIC ACID**

**Directions:** Serving per container 120 gel caps for a one-month supply.

**Suggested use:** As a dietary supplement, take two gel caps AM and 2 gel caps PM for a total of 4 daily with water.

<b>Ingredients</b>	<b>Each</b>	<b>Daily</b>	<b>Adjusted</b>
Phosphatidyl Lipid	350 mg	1400 mg	100 - 3500 mg
Phosphatidylethanolamine (PE)			
Phosphatidylserine (PS)			
Phosphatidylinositol (PI)			
Phosphatidylcholine (PC)			
Alpha Lipoic Acid	25 mg	100 mg	3 - 300 mg daily
<b>Excepients</b>			
Soybean Oil			
Beeswax			
Lecithin			
Gelatin			
Glycerin			
Water			
TOTAL WT w/ Excepients	700 mg	2800 mg	

This is a useful mixture of Phospholipids that mimics biological membrane structures that play a unique and critical role in biological processes. In the body, Phospholipids are unequally distributed across the lipid (fat) overlay and in the plasma membrane of nucleated cells. The Amino Phospholipids (Phosphatidylethanolamine (PE), Phosphatidylinositol (PI), and Phosphatidylserine (PS) are located in the inner leaflet and the Phosphatidylcholine (PC) are more abundant in the outer leaflet. PE, PS, PI and PC each have unique roles in the body and as we age, these Phospholipids diminish thus adversely affecting health. One of the Phosphatidyl Lipids, Phosphatidyl Choline (PC) will help emulsify, mobilize and metabolize cholesterol which causes it to become water soluble in the blood stream thus making it easy to be metabolized and eliminated. PC also provides the body with necessary choline. Studies have shown that within 30 days of a choline deficient diet, liver problems may develop.

The combination of PE, PS, PI, and PC and Alpha Lipoic Acid will help the body to remove toxic deposits, emulsify and dissolve lipids (fat), open up the collateral circulation, lower blood pressure, repair and reduce the size of damaged tissue in patients, serve as cofactors for enzymes, act as major antioxidant within each cell, regulate a wide range of neurological activities (including the functions of movement, coordination and the stimulation of muscle contraction), boost overall health and aid in the absorption of vitamins and minerals.

Alpha Lipoic Acid, used for cellular metabolism to combat many exposed chemicals and viruses, is manufactured in the body and is crucial to detoxification. It helps controls different kinds of free radicals and restores numerous nutrients necessary to the detoxification process. It also retrieves Vitamin E, Glutathione, Vitamin C, CoQ10, and metabolic enzymes.

### C. BOOSTER FOR THE IMMUNE SYSTEM -- MEDICINAL MUSHROOMS

**Directions:** Serving per container 60 tablets for a one-month supply.

**Suggested use:** As a dietary supplement, take one tablet AM and 1 tablet PM daily with water.

<b>Ingredients</b>	<b>Each</b>	<b>Daily</b>	<b>Adjusted Range</b>
Reishi ( <i>Ganoderma lucidum</i> )	250mg	500 mg	150 - 1000
Shiitake ( <i>Lentinula edodes</i> )	250mg	500 mg	150 - 1000

The immune builder contains a unique blend of mushrooms to include equal parts of Shiitake, Maitake,. This product is to boost the immune system.

Reishi, *Ganoderma lucidum*, is a traditional mushroom used to nourish, tonify, and supplement the whole body as it removes toxins. It also calms and nourishes the nervous system, strengthens the lungs, protects and stimulates the liver and helps the body adapt to stress. Reishi helps stimulate the immune system and is recognized as an adjunct for use as an immune system stimulator. The Reishi contains high levels of polysaccharide that help induce the production of interferon, a protein produced inside cells to fight viral infection. Reishi also contains Adenosine which helps calm the central nervous system.

Shiitake, *Lentinula edodes*, is recognized for its strong support of the immune system. Research has shown that Shiitake is also effective against many diseases and is used in the Orient for high blood pressure, balancing cholesterol levels and a liver and kidney tonic. It has also proven effective against Herpes Simplex Type 1 virus, cancer, environmental allergies, candida infections, and frequent colds and flu.